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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4328]

Draft Guidance for Industry on Developing Antimicrobial Drugs to Treat Catheter-Related Bloodstream Infections; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment.'' This draft guidance is one in a series of guidances being developed to assist pharmaceutical manufacturers in developing antimicrobial drug products.

DATES: Written comments on the draft guidance may be submitted by (*insert date 60 days after date of publication in the* **Federal Register**). General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http:// www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance entitled ''Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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FOR FURTHER INFORMATION CONTACT: Renata Albrecht, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2336.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment.'' This is one of a series of guidances under development to assist manufacturers in planning the necessary clinical studies and designing and implementing the clinical protocols for drug products to treat infections. This draft guidance discusses catheter-related bloodstream infections, i.e., bloodstream infections resulting from an infected vascular access device or contaminated infusate. The issues raised in this draft guidance will be discussed at ~~an upcoming~~ a meeting of the Anti-Infective Drugs Advisory Committee, scheduled for October 20, 1999 (64 FR 54335, October 6, 1999).

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on catheter-related bloodstream infections. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 15, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jen Windsor

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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